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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,536

02/08/2007

Donald Schomer

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7815

21971

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WILSON SONSINI GOODRICH & ROSATI

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EXAMINER

DOUGHERTY, SEAN PATRICK

ART UNIT

PAPER NUMBER

3736

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,536	Applicant(s) SCHOMER ET AL.	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-62 is/are pending in the application.
- 4a) Of the above claim(s) 44-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-43 and 50-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/05/2008, 09/29/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the FINAL Office action based on the 10/595536 application filed February 8, 2007. Claims 36-62 are currently pending and have been considered below.

Priority

This application's claim of priority to US Provisional Patent Application Number 60/592099, filed July 29, 2004, is acknowledged.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on June 6 and September 30, 2008, were filed after the mailing date of the initial Office action on May 7, 2008, and are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,954,739 to Bonutti in view of US Patent Number 5,735,865 to Schaumann et al. (Schaumann).

Regarding claims 36, 37, 40, 41 and 42, Bonutti discloses an insertion member comprising a handle (26) for accessing the epidural space¹, an expandable device (46) adapted to be inserted into the epidural space (col. 3, lines 56-58) by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space (col. 2, lines 27-31), the expandable device comprising a handle (24) and a tool including means for engaging the ligamentum flavum (40), wherein the insertion member handle and the expandable device handle do not form a composite handle².

¹Note that the handle (26) extends outside of the tissue (78), as best seen in Fig. 6, and can therefore function as a handle. ²Note that the insertion member handle (26) is separate from the expandable device handle (24) and therefore they do not form a composite handle.

Bonutti does not expressly disclose a cannula having a side aperture proximal its distal end, a trocar/needle, a barbed member coaxially received within said cannula and a cutting member/blade/hook received on the cannula. However, Schaumann is a reference in analogous art that teaches a cannula (1) having a side aperture (9)

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proximal its distal end (7), a trocar/needle (8), a barbed member coaxially received within said cannula (3) and a cutting member/blade/hook (11) received on the cannula.

One having ordinary skill in the art at the time the invention was made would have found it obvious to combine the insertion member of Bonutti with the cannula with side aperture and respective barbed/cutting/blade and trocar/needle members of Schaumann as Bonutti establishes that where the retractor can be left in place while work is being done (col. 4, lines 55-56) and where the work is done with an instrument other than a scope (col. 4, lines 57-58) and Schaumann provides an instrument other than a scope for cutting tissue (see Abstract).

Regarding claims 38, note that the expandable device (46) and handle (26) of Bonutti provide means for engaging a first anatomical structure and means for affixing the first anatomical structure to a second anatomical structure.

Regarding claim 39, note that the expandable device (46) and handle (26) of Bonutti provide means for engaging and retracting the ligamentum flavum and means for anchoring the retracted ligamentum flavum.

Regarding claim 43, Bonutti discloses an injectable medium (col. 2, lines 33-37).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 50-52, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti as modified, in view of US 5,429,139 to Milo et al. (Milo).

Regarding claims 50-52, 57 and 58, Bonutti as modified discloses an injectable medium. Bonutti does not expressly disclose where the injectable medium is an inert base radio-opaque non-ionic myelographic contrast medium. However, Milo discloses injection of radio-opaque fluids (col. 7, lines 35-40). Bonutti as modified in view of Milo discloses the claimed invention except for where the radio-opaque fluid is non-ionic and inert. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the radio-opaque fluid both non-ionic and inert, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. The motivation for doing so would have been to provide a safe fluid used in the expandable device in case it accidentally escapes (col. 2, lines 33-37) as non-ionic and inert fluids are safe for the use of imaging within a body.

Claims 53-56, 60 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti as modified, in view of US 6,602,246 to Sharps et al. (Sharps).

Regarding claims 53-56, 60 and 61, Bonutti as modified discloses the claimed invention except for a steroid. However, Sharps is a reference in analogous art that teaches a steroid. One having ordinary skill in the art at the time the invention was

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made would have found it obvious to include a bioactive/therapeutic/anti-inflammatory agent such as a steroid as the steroid would diminish perineural inflammation of an body portion alleviating pain and providing improved health care (Sharps: col. 55, lines 13-25).

Claims 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti as modified, in view of US 5,985,320 to Edwards et al. (Edwards).

Regarding claim 59, Bonutti as modified discloses a volume of medium in claim 36. Bonutti does not expressly disclose where the volume is injectable at ambient temperatures and more viscous at body temperature. However, Edwards is a reference in analogous art that teaches a volume that is injectable at ambient temperatures and more viscous at body temperature. One having ordinary skill in the art at the time the invention was made would have found it obvious to modify the injectable volume of Bonutti to include be viscous at body temperature as taught by Edwards as this modification would provide compositions and methods for enhancing intracellular delivery of bioactive agents (Edwards: col. 2, lines 6-13).

Claims 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti as modified, in view of US 6,428,486 to Ritchart et al. (Ritchart).

Regarding claim 62, Bonutti as modified does not expressly disclose a cannulated scalpel having a side aperture proximal its distal end, an elongate body housed within said cannulated scalpel and comprising two radially extendable arms

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constructed such that radially extending said arms causes them to extend outward through said side aperture and retracting said arms causes them to close. However, Ritchart is a reference in analogous art that teaches a cannulated scalpel having a side aperture proximal its distal end, an elongate body housed within said cannulated scalpel and comprising two radially extendable arms constructed such that radially extending said arms causes them to extend outward through said side aperture and retracting said arms causes them to close (see Figs. 29 & 30). One having ordinary skill in the art at the time the invention was made would have found it obvious to include the cannulated scalpel of Ritchart with the kit of Bonutti as Ritchart provides an instrument for performing percutaneous biopsy procedures for improving functionality and performance without physical handling of the samples (see Abstract).

Response to Arguments

Applicant's arguments with respect to the rejections in the previous Office action have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/

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Supervisory Patent Examiner, Art Unit 3736